

REMARKS

Reconsideration of this application in view of the above amendments and following remarks is respectfully requested.

Status of the Claims

Claims 154, 163-168, 241-244 and 246-259 are now pending. Claims 155-162 and 169-172 have been canceled. Claims 154, 163-168, 243, 246, 251 and 253 have been amended. Support for the amendment to claim 154 can be found, for example, on page 5, lines 24-25, on page 126, lines 10-11 in the specification as originally filed, and original claim 162 (now canceled). Support for the amendments to claims 251 and 253 can be found, for example, on page 20, line 28, page 17, lines 6-14, and page 28, lines 26-29, in the specification as originally filed. Amendments to claims 163-168, 243 and 246 are to correct informalities only. Claims 256-259 are new. Support for the new claims can be found, for example, on page 126, lines 14-26, in the specification as originally filed. No new matter is being introduced.

Claim Objection

Claim 246 is objected to for being dependent upon canceled claim 245. Claim 246 has been amended to depend on claim 154. This amendment is supported by the fact that the language of canceled claim 245 had been previously incorporated into claim 154 (*see*, amendment filed June 20, 2008). Applicants therefore request this objection be withdrawn.

Claim Rejection -- 35 U.S.C. § 112

Claims 154-172, 241-244, and 246-255 are rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. More specifically, the Examiner alleged that the limitation "wherein the synthetic polymer is not in admixture with any other synthetic polymer that is reactive with the synthetic polymer prior to applying the composition to the tissue or following applying the composition to the biological tissue" was new matter not supported by the specification and the original claims.

Without acquiescing to the Examiner's position and in order to expedite allowance of the claimed subject matter, Applicants have deleted the portion "prior to applying the composition to the tissue or following applying the composition to the biological tissue." The remainder of the above limitation finds its literal support on page 5, lines 24-25. Applicants therefore request this ground of rejection be withdrawn.

Claim Rejection -- 35 U.S.C. § 102

Claims 154-157, 161, 165, 166, 168, 172, 241-246 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pub. No. 2001/0055615 (hereafter "Wallace").

Claim 154 has been amended to specify that the claimed method affects biological processes at a particular type of biological tissue, namely, one that has undergone surgery to excise a tumor. This type of biological tissue tends to develop local recurrence of malignancy, which can be addressed or treated by the claimed method. More specifically, the claimed method is directed to applying to such biological tissue a composition comprising essentially of a synthetic polymer and a drug, the synthetic polymer comprising poly(alkylene oxide) functionalized with multiple activated groups Y, Y is reactive with functional groups X, wherein the synthetic polymer is not in admixture with any other synthetic polymer that is reactive with the synthetic polymer, and allowing the synthetic polymer to form covalent bonds with the biological tissue.

Amended claim 154 is not anticipated by Wallace because Wallace does not disclose or suggest applying a composition of essentially a single synthetic polymer and a drug to biological tissue that has undergone surgery to excise tumor, whereby the synthetic polymer forms covalent bonds with the biological tissue. Instead, Wallace describes applying crosslinked hydrogels formed by two synthetic polymers to tissue sites. Further, Wallace does not describe the particular tissue as claimed in amended claim 154. Nor does Wallace describe forming covalent bonds with the tissue. Rather, the two synthetic polymers form covalent bonds with each other. Accordingly, Wallace does not anticipate amended claim 154 or its dependent claims.

Further, new claim 256 has additional novel features that are not disclosed or suggested in Wallace. New claim 256 specifies that the claimed method affects local recurrence of tumor at the biological tissue. Wallace does not mention or suggest treating tumor excision site or local recurrence of tumor. Accordingly, new claim 256 and its dependent claims are novel over Wallace.

Claims 154, 155, 161, 169-172, 241-246 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,166,130 (hereafter "Rhee").

Amended claim 154 is not anticipated by Rhee because Rhee, like Wallace, is directed to applying crosslinked hydrogels formed by two synthetic polymers to tissue sites. Rhee does not, however, describe the particular tissue as claimed in amended claim 154. Nor does Rhee describe forming covalent bonds with the tissue. Rather, the two synthetic polymers form covalent bonds with each other. Accordingly, Rhee does not anticipate amended claim 154 or its dependent claims.

For the same reason as stated above, new claim 256 and its dependent claims are also novel in view of Rhee.

From the forgoing, Applicants respectfully submit that neither Wallace nor Rhee teaches or suggests the features of claim 154 (as amended) and its dependent claims. Applicants therefore request these grounds of rejection be withdrawn.

Claim Rejection -- 35 U.S.C. § 103

Claims 154-172, 241-244 and 246-255 are rejected under 35 U.S.C. § 103(a) as being obvious over Wallace or Rhee or U.S. Patent No. 6,458,889 (hereafter "Trollsas") in view of U.S. Patent No. 5,965,566 (hereafter "Greenwald") and U.S. Patent No. 6,534,693 (hereafter "Fischell").

Amended claim 154 is not obvious in view of the cited references because the combination of Wallace (or Rhee or Trollsas) with two secondary references do not establish a *prima facie* case of obviousness.

As discussed above, Wallace (or Rhee or Trollsas) does not disclose or suggest at least two features of the claimed method, namely, (1) the specific biological tissue that has

undergone surgery to excise a tumor, and (2) the composition consisting essentially of a single synthetic polymer and a drug, wherein the synthetic polymer forms covalent bonds with the biological tissue. Greenwald is relied upon to show anti-cancer drugs (e.g., taxol) can be conjugated to prodrugs. Fischell is relied upon to show anti-proliferative drugs (e.g., taxol) can be combined with implants. Applicants submit that there are any number of references that can be cited that disclose anti-cancer or anti-proliferative drugs for drug delivery to biological tissues. However, the claimed features that are missing in Wallace (or Rhee or Trollsas) are also lacking in Greenwald and Fischell. Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established as to the subject matter of amended claim 154 (or its dependent claims). Accordingly, Applicants request this ground of rejection be withdrawn.

Obviousness-type Double Patenting Rejection

Claims 154, 155, 162, 241-244, and 247-255 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 18-21, 89-91, 93-95, 108, 110, and 131-141 of copending Application No. 10/749,117.

Applicants submit that Application No. 10/749,117 has gone abandoned. Thus, Applicants request that this ground of rejection be withdrawn.

Applicants wish to make known to the Office copending Application No. 12/259,916, which is a continuation application of Application No. 10/749,117 (now abandoned).

Conclusion

In view of the above amendments and remarks, allowance of claims 154, 163-168, 241-244 and 246-259 is respectfully requested. A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
SEED Intellectual Property Law Group PLLC

/Hai Han/
Hai Han, Ph.D.
Registration No. 54,150

HXH:mcs

701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

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